[0013] Accordingly, there remains a need for a better hydrophilic catheter assembly that avoids the above-mentioned problems. What is needed is an easy-to-use, disposable catheterization assembly that includes a hydrophilic catheter and is practical for use by health care providers and by individuals alike, and which is suitable for self-catheterization.

SUMMARY OF THE INVENTION

[0014] The present invention provides a new catheter device or assembly that permits essentially sterile catheterization of the bladder and establishment of free drainage of urine from the discharge end of the catheter without using conventional sterile field technique. The new catheter assembly is an alternative to, or an improvement over, existing "unitized" self-lubricating catheterization assemblies. In accordance with certain exemplary embodiments of the present invention, a urinary catheterization device is provided that generally includes a (a) catheter introducer including a first guide section including an inlet for receiving a urinary catheter tip and a second guide section including an aperture for releasing the catheter tip, the aperture adapted for contacting a urethral opening; (b) a catheter including a tip having at least one urine inlet, a urine outlet, and an outer surface, at least a urethra-insertable portion of the outer surface being hydrophilic, the catheter tip being initially disposed in the first guide section; (c) a flexible walled sheath comprising first and second ends, a lumen, and a length that is less than that of the catheter, the sheath first end being sealingly attached to the catheter at a non-urethra-insertable location on the catheter adjacent to the outlet, and the sheath second end being sealingly attached to the first guide section, whereby the catheter tip is retained in the first guide section and prevented from slipping into the sheath lumen, the inlet and at least the urethra-insertable portion of the catheter being enclosed in the sheath lumen, the sheath adapted for containing a liquid for wetting the hydrophilic catheter or at least the urethra-insertable portion thereof; (d) a diaphragm disposed in the catheter introducer between the first and second guide sections, and adapted for being pierced by the catheter tip and for deterring or preventing leakage of the wetting liquid from the first guide section into the second guide section before and after being pierced by the catheter tip.

[0015] In certain embodiments, the diaphragm includes an extension that protrudes into the second guide section and is substantially conformable to the shape of the catheter tip and to the circumference of a moving catheter. In certain embodiments, the first guide section includes a cavity in fluid flow communication with the sheath lumen, and the sheath lumen and/or the first guide section contains an amount of the wetting liquid sufficient to wet the hydrophilic outer surface of the catheter to render the catheter lubricious. In certain embodiments, the second guide section comprises a cavity adapted for initially containing at least an amount of the wetting liquid sufficient to wet the hydrophilic outer surface of the catheter to render the catheter lubricious, and wherein the diaphragm is capable of preventing flow of the wetting liquid into the first guide section prior to the diaphragm being opened. In some embodiments, the second guide section is resiliently compressible. In certain embodiments, the flexible walled sheath is impermeable to the wetting liquid and may also comprise a grip enhancing surface.

[0016] In certain embodiments, an above-described catheterization assembly also includes a urine collection bag attached to a non-urethra-insertable site on the catheter. The collection bag is adapted for receiving the catheter urine outlet.

[0017] Advantageously, the urine outlet is separated from the sheath lumen so that the sheath lumen is not in fluid communication with the collection bag, and thus the wetting liquid is prevented from entering the urine collection bag. In certain embodiments, the sheath first end is sealingly attached to the catheter adjacent to the site of attachment of the urine collection bag, or adjacent thereto.

[0018] In certain embodiments, the sheath is of approximately equal length to that of the urethra-insertable catheter portion and the catheter tip is retained in the first guide section and is prevented from slipping into the sheath interior when the device is fully extended.

[0019] In some embodiments, an above-described catheterization device includes a removable closure sealing the catheter outlet. In certain embodiments, catheterization device includes a body-contacting collar and a frustoconical segment having its smallest outer diameter adjoining the collar.

[0020] In certain embodiments, the first and second guide sections are releasably joined together such that the diaphragm is removable, and in other embodiments they are fixedly joined together with the diaphragm disposed therebetween. In certain embodiments of an above-described catheterization device the diaphragm includes a conformable fluid barrier.

[0021] Also provided in accordance with certain embodiments of the present invention is a kit for catheterizing a urinary bladder, including a catheterization device as described above, a disposable package enclosing the catheterization device; and at least one antiseptic swab. In certain embodiments, the kit includes an attachable urine collection vessel having volumetric indicia.

[0022] Further provided in accordance with certain embodiments of the present invention is a method of deterring or preventing spillage of a wetting liquid during catheterization of a urinary bladder. The method includes: (a) providing an above-described device including an attached urine collection vessel, or providing an above-described device without an attached urine collection vessel and providing for urine disposal or collection; (b) placing the catheter introducer outlet against the urethral opening of an individual in need of catheterization; (c) grasping the flexible walled sheath and wetted hydrophilic catheter together at one or more first position or series of positions along the urethra-insertable length of the catheter, and urging the catheter tip into the diaphragm such that the diaphragm is pierced and such that a portion of the sheath is caused to collapse toward the first guide section; (d) re-grasping the flexible walled sheath and wetted catheter together at one or more second position or series of positions along the urethra-insertable length of the catheter, and moving the catheter tip through the pierced diaphragm, whereby a further portion of the sheath is caused to collapse toward the first guide section and the pierced diaphragm or a portion thereof forms a leak resistant slidable seal around the moving catheter; (e) re-grasping the flexible walled sheath and